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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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01/29/2002

Samuels, Gauthier & Stevens, LLP
Suite 3300
225 Franklin Street
Boston, MA 02110

EXAMINER

ROBINSON, BINTA M

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 01/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/699,732

Applicant(s)

HEARN, MICHAEL J.

Examiner

Binta M. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 3-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

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Detailed Action

The examiner notes applicant's election of species at paper no. 8 where R1 = H, R2 = substituted phenyl and R3=C1 to C2 alkyl. This species will now be used as a reference point to create a natural genus and to further restrict the application under 35 U. S. C. 121.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2,17, drawn to the compound of formula I where R1 is H, R2 is phenyl optionally substituted with nonheterocyclic moieties and a method of producing a compound of formula I where R1 and R2 are as defined above, classified in class 546, subclass 325.
- II. Claims 1-20, drawn to the compound of formula I where R1 is H, or CH₂, R2 is all other moieties not described in Group I and the method of producing a compound of formula II, III, and IV, classified in various classes and subclasses.

The inventions are distinct, each from the other because of the following reasons:

In the instant case the different inventions have achieved a separate status in the art, have separate fields that aren't coextensive, and are capable of supporting separate patents. Further, a prior art reference that would anticipate the claims under 35 USC 102(b) would not render obvious the same claim(s) under 35 U. S. C. 103 (a) with respect to another member. Searching the entire genus would be a burden on the USPTO in terms of time and expense.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The unelected portions of claims 1-2, 17 and claims 3-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the whole genus of formula I substituted. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte* Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

The cumulative effect of all of the substituted compounds makes it impossible to ascertain what the metes and bounds of the invention are.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In *re Wands*, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

.In terms of the fifth Wands factor, the inhibition ranges from 99% which is great to 0 % which is poor. There are massive differences in inhibition for small changes in structure. For example, compound 126719 has a % inhibition of 84% whereas compound 125304 has an inhibitions of 15%. Compound 125304 has a bromine substituted on the phenyl ring. Compound 126719 has a chlorine substituted on the phenyl ring. The level of predictability regarding inhibition is low. In terms of the sixth Wands factor, the amount of direction provided by the inventor is poor, because the applicant does not test compounds for their affects on the specific diseases claimed. The applicant must show tests results for the cancers claimed involving specific cell lines. In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of

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the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim(s) 1 and 17 in part are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 1, line 6, page 101 and in claim 17 in part, line 9, page 108, the phrase "substituted phenyl" is indefinite. It is unclear as to what the metes and bounds of this substitution are.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim(s) 1-2, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Fox et. al. (See Reference U). Fox et. al. discloses the instant compound, II. At page 983, see the instant compound.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Binta Robinson

January 28, 2002

Alan L Rotman

ALAN L. ROTMAN
PRIMARY EXAMINER

SPE NO. 1625